REMARKS

Applicants, by the amendments presented above, have made a concerted effort to present claims which more clearly define over the prior art of record, and thus to place this case in condition for allowance.

Claims 1-5, 7-16, 33, 36-44 and 48-59 have been examined in this application. Applicants affirms the election of the species embodied in Figure 1. The Examiner has considered claims 33 and 36-44 which previously had been withdrawn. Claims 45-47 remain withdrawn.

Claim Objections

Claims 8, 10, 12, 15, 48, 50 and 59 were objected to. Reconsideration and withdrawal of the objection is requested in view of the amendments made herein.

The transitional phrase has been added to claim 8.

Claims 10 and 12 have been clarified to recite the two sensors as separate elements from the humidity sensor.

Claim 15 has been amended to be consistent with claim 1.

The phrase has been deleted in claim 48.

The use of "said outlet" in claim 50 has been deleted.

Claim 59 has been amended to stated "configured".

Reconsideration of the claims and withdrawal of the rejection is requested.

Claim Rejections - 35 U.S.C. §112, second paragraph

Claims 15, 33 and 36-44 were rejected under 35 U.S.C. §112, second paragraph. Reconsideration and withdrawal of the objection is requested in view of the amendments made herein.

Claim 15 has been amended to correctly specify "said humidity sensor" instead of -- said temperature sensor --.

Claim 33 has been amended to include all of the limitations of previously canceled claim 17 and to remove some of the "means" language.

Claims 36-38, 41, 43, 44 have been amended to include all of the limitations found in previously canceled claim 34 and to modify some of the "means" language.

Claim Rejections - 35 U.S.C. §102(b)

Claim 59 was rejected under 35 U.S.C. §102(b) as allegedly being anticipated by Yoshikazu - 092342-47. Reconsideration of the rejection is requested.

Claim 59 specifies "a controller or processor configured or programmed to receive as inputs said indication of the absolute humidity of said gases flow, and energise said chamber heater based on said absolute humidity to achieve a predetermined absolute humidity at said outlet, and configured or programmed to vary said predetermined absolute humidity to substantially avoid condensation in said conduit." Yoshikau does not attempt to control the absolute humidity on delivery to the conduit. Yoshikau does not vary the set absolute humidity level at the chamber to avoid condensation in the conduit. Yoshikau controls the absolute humidity at a different location and uses the tubing heater to avoid condensation. Therefore, Applicants submit that claim 59 is not anticipated by Yoshikau and reconsideration is requested.

Claim 59 was rejected under 35 U.S.C. §102(b) as being anticipated by EP 9 885 623 to Gradon. Reconsideration of the rejection is requested.

Claim 59 specifies "a controller or processor configured or programmed to receive as inputs said indication of the absolute humidity of said gases flow, and energise said chamber heater based on said absolute humidity to achieve a predetermined absolute humidity at said outlet, and configured or programmed to vary said predetermined absolute humidity to substantially avoid condensation in said conduit." Gradon does not attempt to control absolute humidity at all and again uses a conduit heater to avoid condensation as opposed to optimizing the absolute humidity. Therefore, Applicants submit that claim 59 is not anticipated by Gradon and reconsideration is requested.

Allowable Subject Matter

Claim 1-5, 7, 9, 11, 13, 14, 16, 49 and 51-58 have been allowed.

The Examiner indicated that claims 33 and 36-44 would be allowable if rewritten to overcome the rejection under 35 U.S.C. §112, second paragraph, set forth on page 4 of the Office Action, and to include all of the limitations of the base claim and any intervening claims.

Claim 33 has been amended to include all of the limitations of previously canceled claim 17 and to remove some of the "means" language. Applicants submit that this does not effect the allowability of the claim. Reconsideration and allowance is requested.

Claims 36-38, 41, 43, 44 have been amended to include all of the limitations found in previously canceled claim 34 and to modify some of the "means" language. Applicants submit that this does not effect the allowability of the claims. Reconsideration and allowance is requested.

Claims 8, 10, 12, 15, 48 and 50 were not rejected based upon prior art. Therefore, because the informalities have been resolved, Applicants submit that these claims are in condition for allowance.

Certified Copy

The Examiner has indicated that the Certified Copy of the priority document New Zealand 503495 has not been received. Applicants filed the Certified Copy on 23 May 2001 and a copy of the returned postcard is enclosed. To avoid further delays in prosecuting this application, however, a new Certified Copy is concurrently filed herewith.

Information Disclosure Statement

Applicants submitted Information Disclosure Statements, copies enclosed, on July 18, 2003; October 14, 2003; October 15, 2003 and January 27, 2004. Copies of the return postcards are enclosed indicating that the Information Disclosure Statements were received. Applicants request consideration of these Information Disclosure Statements and return of the initialed forms PTO-1449.

A Petition for a One-Month Extension of Time is concurrently submitted herewith to extend the date for response up to and including April 9, 2004.

In view of the above Amendments and Remarks, Applicants respectfully submit that the claims of the application are allowable. Should the Examiner have any questions regarding this Amendment, the Examiner is invited to contact one of the undersigned attorneys at (312) 704-1890.

Respectfully submitted,

Dated: June 17, 2004

By: _____

Raiford A. Blackstone, Jr., Reg. No. 25,156
Linda L. Palomar, Reg. No. 37,903

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629539

Case 92
1171/39258

RAB/LLP/tes
May 23, 2001

Applicant: Seakins et al.
Serial No.: 09/808,567
Filed: March 14, 2001
For: BREATHING ASSISTANCE APPARATUS

Enclosed:

Transmittal of Certified Copy Regarding Convention Claim Under 35 USC §119, Certified Copy of New Zealand Provisional Specification with an application for Letters Patent No. 503495; Certificate of Mailing and this postcard

Receipt Acknowledged:_____

F/U: 06/23/01

HON. COMMISSIONER FOR PATENTS:

Kindly stamp card with date of receipt of attached material and return to attorneys of record.

TREXLER, BUSHNELL, GIANGIORGI,
BLACKSTONE & MARR, LTD.
105 West Adams Street, 36th Floor
Chicago, IL 60603-6299

02

Case 92
1171/39258

June 14, 2001
RAB/LLP/tes

Applicant: Seakins et al.
For: BREATHING ASSISTANCE APPARATUS
Serial No.: 09/808,567
Filed: March 14, 2001

Enclosed: INFORMATION DISCLOSURE STATEMENT; Form PTO-1449; four cited references; Certificate of Mailing; and this postcard.

Receipt Acknowledged:_____ F/U: 07/14/01

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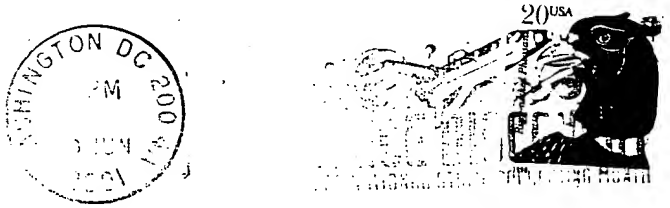

TREXLER, BUSHNELL, GIANGIORGI,
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105 West Adams Street, 36th Floor
Chicago, IL 60603-6299

Case 92
1171/39258

July 18, 2003
RAB/LLP/tes

Applicant: Seakins et al.
For: **BREATHING ASSISTANCE APPARATUS**
Serial No.: 09/808,567
Filed: March 14, 2001

Enclosed: **SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT; Form PTO-1449;** 4 cited references; Certificate of Mailing; and this postcard.

Receipt Acknowledged:_____ F/U: 08/18/03

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COPY

Trexler, Bushnell, Giangiorgi, Blackstone & Marr, Ltd.
105 W. Adams Street, 36th Floor
Chicago, Illinois 60603

Case 92
1171/39258

October 14, 2003
RAB/LLP/tes

Serial No.: 09/808,567
Filed: March 14, 2001
For: BREATHING ASSISTANCE APPARATUS
Applicant: SEAKINS et al.

Enclosed: Form PTO-1083 (in duplicate); AMENDMENT; A copy of the Information Disclosure Statement filed on July 18, 2003; one sheet of drawings; An Information Disclosure Statement; PTO-1449; 19 cited references; A check in the amount of $180.00; Certificate of Express Mailing; and this postcard.
Express Mailing Number ***EL966274035US***
Receipt Acknowledged: _____ F/U: 11/14/03

rule applied

ASSISTANT COMMISSIONER FOR TRADEMARKS:

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BLACKSTONE & MARR, LTD.

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CHICAGO, IL 60603-6299**

Case 92
1171/39258

January 27, 2004
RAB/LLP/tes

Applicant: SEAKINS et al.
Serial No.: 09/808,567
For: BREATHING ASSISTANCE APPARATUS
Filed: March 14, 2001

Enclosed: **SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT; Form PTO-1449**; 1 cited reference; Certificate of Mailing; and this postcard.

Receipt Acknowledged: _____ F/U: 02/27/04

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TREXLER, BUSHNELL, GIANGIORGI & BLACKSTONE
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Chicago, Illinois 60603

TREXLER BUSHNELL, GIANGIORGI,
BLACKSTONE & MARR, LTD.

Ministry of Economic Development
Manatū Ōhanga
Intellectual Property Office of New Zealand

CERTIFICATE

This certificate is issued in support of an application for Patent registration in a country outside New Zealand pursuant to the Patents Act 1953 and the Regulations thereunder.

I hereby certify that annexed is a true copy of the Provisional Specification as filed on 21 March 2000 with an application for Letters Patent number 503495 made by FISHER & PAYKEL LIMITED.

Dated 22 January 2004.

Neville Harris
Commissioner of Patents, Trade Marks and Designs

COMMISSIONER OF PATENTS, TRADEMARKS & DESIGNS
NEW ZEALAND

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503495

NEW ZEALAND

PATENTS ACT, 1953

PROVISIONAL SPECIFICATION

Improvements to Humidifiers

We, FISHER & PAYKEL LIMITED, of 78 Springs Road, East Tamaki, Auckland, do hereby declare this invention to be described in the following statement:

FIELD OF THE INVENTION

The present invention relates to the use of an humidification system particularly, but not solely, for providing respiratory assistance to patients receiving mechanical ventilation or respiratory support.

DESCRIPTION OF THE PRIOR ART

A number of methods are known in the art for supplying humidified gases to a patient requiring breathing assistance. Such prior art humidifiers generally comprise a source of pressurised air (or other mixture of gases), a humidification chamber including a source of water and a heating means to vaporise the water, and a conduit to convey the humidified gases to the patient or user.

For example US patent 4,038,980 describes a "flash vaporisation" humidifier where water drips onto a low thermal mass heater to create respiratory humidity. It mentions "control means may be provided automatically to regulate the water supply rate in response to means sensing the relative humidity", however they prefer a manual control of water flow rate. Thus it incorporates a humidity sensor and controls the water rate, as opposed to controlling the amount of electrical heating.

US patent 5,092,326 also describes the use of a humidity sensor in a humidifier. It describes a high frequency ventilation system that incorporates a heated humidifier and a humidity sensor, where these are linked to a central microprocessor. Claims 10 and 36 include "means are provided to moisten said gas mixture supplied to the airway, and said microprocessor controls the amount of moisture supplied to the gas mixture." While it discloses a humidity sensor at the patient airway, it doesn't describe the actual humidification configuration to be used.

US patent 5,769,071 describes a humidifier incorporating a heat and moisture exchanger (HME), supply of water to the HME, heater element and humidity sensor. The humidity sensor can control humidity via water supply rate or temperature (via the heater element). Also the humidity sensor is described as being at the patient airway.

US patent 5,988,164 describes a heated breathing tube system for use with a humidifier. This uses a relative humidity sensor (located near the patient) to control the amount of heating provided by the heated breathing circuit so that the gas is at a constant level of relative humidity. The heated breathing circuit may use either electrical heating, or heating via warm recirculating water in a tube. Also described is a method of control of the electric heater wire or heated water tube based on the output of relative humidity sensor.

The previously mentioned US patents 4,038,980 and 5,769,071 both describe humidifiers where the humidification chamber is located close (proximal) to the patient. These have the disadvantage of introducing weight, heat and complexity near the patient which is inconvenient and could be painful to the patient. Of the cited prior art only US patent 5,988,164 specifically describes the humidification chamber as being located remotely from the patient.

There are several disadvantages of the prior art systems *using a humidification chamber located remotely from the patient. *It is normally assumed that gases leaving such prior art humidifiers are saturated with water vapour (100% relative humidity). However there is no guarantee that the gases leaving such humidifiers are in fact saturated with water vapour. In certain circumstances (e.g. with the incoming air already warm), the gases leaving such humidifiers can be significantly less than 100% relative humidity. This is because as they are typically controlled to achieve a desired outlet gas temperature, which in such cases may not be much more than the incoming air.

Another drawback of the prior art systems is that condensation can occur in the (sometimes heated) conduits connecting the patient to the respiratory assistance

equipment. This may occur if the temperature profile along such conduits is not even and allows some parts of the conduit to be colder than the gas at these points.

A third disadvantage of such prior art systems is where the gas leaving the humidifier is at 100% relative humidity it must be heated immediately by some form of conduit heater or it may lose heat through the walls of the conduit, which results in condensation and therefore a drop in the amount of absolute humidity contained in the gas.

Another fourth disadvantage of the prior art systems is the need for a sensor very near to the patient, which adds to the weight and bulk of equipment at the patient's airway.

A fifth disadvantage of the prior art systems is that intermittent or varying flow rates will cause the absolute humidity that is generated by the humidifier to be uneven. This is because the flow rate is varying faster than any control loop that might operate in such humidifiers. Air which passes through the humidifier at a high flow rate has had little time to be heated and humidified, while air that passes through the chamber at a low flow rate will be hotter and contain higher absolute humidity. Consequently it is difficult for the heated conduit in such prior art systems to transport these high humidity boluses without condensation and consequent loss of absolute humidity.

SUMMARY OF THE INVENTION

It is therefore an object of the present invention to provide a humidification system which goes some way to overcoming the above mentioned disadvantages, or which will at least provide the public with a useful choice.

Accordingly in a first aspect the present invention may be broadly said to consist in humidification apparatus for humidifying a gases flow to be supplied to a patient or other person in need of such gases comprising:

humidification chamber means and having an inlet and an outlet to allow said gases flow to pass through said humidification chamber means,

chamber heating means provided adjacent said humidification chamber means and adapted to vaporise liquid water in said humidification chamber means in order to provide water vapour to said gases flow passing through said humidification chamber means,

gases transportation pathway means connected to said outlet of said humidification chamber means to convey said gases flow to said patient or other person in need of such gases, and

humidity sensing means for providing an indication of the absolute humidity of said gases flow at least at one point in the flow path through said apparatus of said gases flow.

Preferably said humidity sensing means comprising a first absolute humidity sensor in substantial proximity to said outlet of said humidification chamber means.

Preferably said gases transportation pathway means having a patient end, distal to said end connected to said outlet of said humidification chamber means, and said humidity sensing means further comprising a second absolute humidity sensor in substantial proximity to said patient end of said gases transportation pathway means.

Preferably said apparatus further comprising control means which receives as inputs the output from said humidity sensing means and storing a program which estimates the rate of condensation of the vapour from said gases in said gases transportation pathway means.

Preferably said estimate of the rate of condensation is based on the difference between the absolute humidity at said outlet of said humidification chamber means, as indicated by the output of said first absolute humidity sensor, and the absolute humidity

at said patient end of said gases transportation pathway means, as indicated by the output of said second absolute humidity sensor.

Preferably said apparatus further comprising conduit heating means adapted to heat

said gases flow in said gases transportation pathway means and/or said gases transportation pathway means, and said control means storing a program adapted to control the power supplied to said conduit heating means depending on at least said estimate of the rate of condensation, in order to minimise any condensation of the vapour from said gases in said gases transportation pathway means.

Preferably said apparatus further comprising conduit heating means adapted to heat said gases flow in said gases transportation pathway means and/or said gases transportation pathway means, and said control means storing a program which causes said control means to:

i) control the power supplied to said conduit heating means depending on at least said estimate of the rate of condensation, in order to substantially vaporise any liquid condensate present in said gases transportation pathway means; and

ii) control the power supplied to said conduit heating means depending on at least said estimate of the rate of condensation, in order to minimise any condensation of the vapour from said gases in said gases transportation pathway means.

Preferably said steps (i) and (ii) are repeated continually at regular intervals.

Alternatively said steps (i) and (ii) are alternated at regular intervals.

Preferably said humidity sensing means further comprising a first temperature sensor in substantial proximity to said outlet of said humidification chamber means.

Preferably said apparatus further comprising conduit heating means adapted to heat said gases flow in said gases transportation pathway means and/or said gases transportation pathway means, and said control means storing a program adapted to control the power supplied to said conduit heating means depending on at least said estimate of the rate of condensation, in order to minimise any condensation of the vapour from said gases in said gases transportation pathway means as well as convey said gases

flow to said patient or other person in need of such gases substantially at a predetermined level of absolute humidity.

Preferably said humidity sensing means comprising of at least a temperature sensor and a relative humidity sensor providing an indication of the temperature and relative humidity at least at one point in the flow path through said apparatus of said gases flow.

Preferably said apparatus further comprising flow sensing means adapted to provide an indication of the rate of flow of said gases flown through said apparatus.

Preferably said flow sensing means comprising a heated element adapted to maintain a substantially constant temperature and being provided in the flow path of said gases through said apparatus, the heat loss therefrom providing an indication of the rate of flow of said gases.

Preferably said humidity sensing means further comprising disposable cover means for providing a substantial barrier to microorganisms between said flow of gases and said temperature sensor.

Preferably said humidity sensing means further comprising porous disposable cover means for providing porous material as a substantial barrier to microorganisms between said flow of gases and said absolute humidity sensor.

In a second aspect the present invention may be broadly said to consist in humidification apparatus for humidifying a gases flow to be supplied to a patient or other person in need of such gases comprising:

humidification chamber means and having an inlet and an outlet to allow said gases flow to pass through said humidification chamber means,

chamber heating means provided adjacent said humidification chamber means including wet heating means adapted to vaporise liquid water in said humidification chamber means in order to provide water vapour to said gases flow passing through said humidification chamber means and dry heating means adapted to directly heat said gases

flow passing through said humidification chamber means,

gases transportation pathway means connected to said outlet of said humidification chamber means to convey said gases flow to said patient or other person in need of such gases, and

control means storing a program which causes the control means to *energise* said wet heating means and said dry heating means to achieve a desired level of absolute humidity.

Preferably said apparatus further comprising humidity sensing means for providing an indication of the absolute humidity of said gases flow at least one point in the flow path through said apparatus of said gases flow.

Preferably said chamber heating means comprises a metal spiral element.

Alternatively said chamber heating means comprises a heated porous ceramic member adapted to be in contact with said liquid water and said gases flow.

In a further alternative said chamber heating means comprises a heated semipermeable membrane adapted to be in contact with said liquid water and said gases flow.

Preferably said humidification chamber means further having a humidification bypass means, for allowing a portion of said gases to flow to pass from said inlet of said humidification chamber means to said outlet of said humidification chamber means substantially without humidification.

Preferably said humidification chamber means further having a bypass conduit means at least partially passing through said quantity of water for conveying a portion of said gases flow from said inlet of said humidification chamber means to said outlet of said humidification chamber means, and a valve means provided in said bypass conduit means to thereby control the flow rate of the portion of said gases flow in said bypass conduit

means.

Alternatively said humidification chamber means further having a bypass conduit means for conveying a portion of said gases flow from said inlet of said humidification chamber means to said outlet of said humidification chamber means including a bypass heating means adapted to heat the portion of said gases flow in said bypass conduit means and/or said bypass conduit means, and a valve means provided in said bypass conduit means to thereby control the flow rate of the portion of said gases flow in said bypass conduit means.

Preferably the restriction provided by said valve means on the flow rate of the portion of said gases flow in said bypass conduit means is in use permanently set.

Preferably the restriction provided by said valve means on the flow rate of the portion of said gases flow in said bypass conduit means is in use manually adjustable.

Preferably said control means storing a program adapted to control the restriction provided by said valve means on the flow rate of the portion of said gases flow in said bypass conduit means based on the instantaneous flow rate of said gases flow through said humidification chamber means, in order that the gases flow exiting from said humidification chamber means is of substantially constant humidity.

Preferably said valve means comprising an electromechanical actuator connected to a valve member wherein controlled energisation of said electromechanical actuator varies the position of said valve member thereby varying the restriction provided by said valve means on the flow rate of the portion of said gases flow in said bypass conduit means.

Alternatively said valve means comprising either a valve member connected to an elastic member or an elastic valve member wherein said valve being positioned in said

gases flow at said inlet to humidification chamber means and the position of said valve member or said elastic valve member thereby determines the portion of said gases flow in said bypass conduit means.

Preferably the position of said valve member or said elastic valve member providing an indication of the rate of flow of said gases flow at said inlet to humidification chamber means.

Preferably said apparatus further comprising gases heating means adjacent to said inlet of said humidification chamber means, for heating of said flow of gases prior to being humidified.

Alternatively said apparatus further comprising gases heating means adjacent to said outlet of said humidification chamber means, for heating of said flow of gases subsequent to being humidified.

Preferably said gases transportation pathway means includes insulation means adapted to minimise the rate of heat energy lost by said gases flow in said gases transportation pathway means, said control means storing a program adapted to energise said chamber heating means to minimise the condensation of the vapour from said gases in said gases transportation pathway means while providing predetermined levels of absolute humidity.

In a third aspect the present invention may be broadly said to consist in humidification apparatus for humidifying a gases flow to be supplied to a patient or other person in need of such gases comprising:

humidification chamber means and having an inlet and an outlet to allow said gases flow to pass through said humidification chamber means,

chamber heating means provided adjacent said humidification chamber means and adapted to vaporise liquid water in said humidification chamber means in order to provide water vapour to said gases flow passing through said humidification chamber means,

gases transportation pathway means connected to said outlet of said humidification chamber means to convey said gases flow to said patient or other person in need of such gases, and

regulated conduit heating means adapted to regulate the temperature profile of said gases flow along said gases transportation pathway means and/or of said gases transportation pathway means.

Preferably said regulated conduit heating means comprising at least one section of positive temperature coefficient material wherein the localised electrical resistance of each said section of said material is positively related to the localised temperature of said material.

Alternatively said regulated conduit heating means comprising at least one section of negative temperature coefficient material wherein the localised electrical resistance of said material is negatively related to the localised temperature of said material.

Preferably said regulated conduit heating means comprising a plurality of sections of positive temperature coefficient material wherein the localised electrical resistance of each said section of said material is positively related to the localised temperature of said material, and at least two electrical conductors running along said gases transportation pathway means, each said conductor being electrically connected to a portion of each said section of positive temperature coefficient material.

Preferably said gases transportation pathway means further comprising an inspiratory conduit means in fluid communication with said outlet of said humidification chamber, a connector means in fluid communication with said inspiratory conduit means, a flexible tube extension means in fluid communication with said connector means and patient interface means in fluid communication with said flexible tube extension means adapted to convey said gases flow to said patient.

Preferably said flexible tube extension means comprising flexible tube extension

heating means including at least one section of positive temperature coefficient material wherein the localised electrical resistance of each said section of said material is positively related to the localised temperature of said material, and at least two electrical conductors running along said flexible tube extension means, each said conductor being electrically connected to a portion of each said section of positive temperature coefficient material.

Preferably said patient interface means comprising patient interface heating means including at least one section of positive temperature coefficient material wherein the localised electrical resistance of each said section of said material is positively related to the localised temperature of said material, and at least two electrical conductors running along said patient interface means, each said conductor being electrically connected to a portion of each said section of positive temperature coefficient material.

Preferably said apparatus further comprising sensing means for providing an indication of the absolute humidity of said gases flow at said outlet of said humidity chamber means.

Alternatively said apparatus further comprising sensing means for providing an indication of the temperature of said gases flow at said outlet of said humidity chamber means.

Preferably said gases transportation pathway means comprising a double walled inspiratory conduit and said regulated conduit heating means comprising the provision of warm fluid circulated between the inner wall and outer wall of said double walled inspiratory conduit.

In a forth aspect the present invention may be broadly said to consist in humidification apparatus for humidifying a gases flow to be supplied to a patient or other person in need of such gases comprising:

humidification chamber means and having an inlet and an outlet to allow said gases flow to pass through said humidification chamber means,

chamber heating means provided adjacent said humidification chamber means and adapted to vaporise liquid water in said humidification chamber means in order to provide water vapour to said gases flow passing through said humidification chamber means, and

chamber manifold means adapted to connect said inlet of said humidification chamber means to a supply conduit means being in fluid communication with a gases supply means for supplying said gases flow at a desired pressure, and adapted to connect said outlet of said humidification chamber means to a gases transportation pathway means for conveying said gases flow to said patient or other person in need of such gases, and including provisions for at least one sensing means to provide an indication of at least one measurable quantity of said gases flow at least at a location in proximity to said outlet of said humidification chamber means.

Preferably said chamber manifold means further including chamber manifold heating means adapted to heat said gases flow through said chamber manifold means and/or said chamber manifold means.

Preferably said chamber manifold means is attached to and removable from said humidification chamber means.

This invention may also be said broadly to consist in the parts, elements and features referred to or indicated in the specification of the application, individually or collectively, and any or all combinations of any two or more of said parts, elements or features, and where specific integers are mentioned herein which have known equivalents in the art to which this invention relates, such known equivalents are deemed to be incorporated herein as if individually set forth.

The invention consists in the foregoing and also envisages constructions of which the following gives examples.

BRIEF DESCRIPTION OF THE DRAWINGS

One preferred form of the present invention will now be described with reference to the accompanying drawings in which;

Figure 1 shows an example of an humidification system, comprised of three parts,

Figure 2 shows a chamber which incorporates a metal element,

Figure 3 shows a chamber using a porous material to provide a heating and humidifying function,

Figure 4 shows a chamber using a semipermeable membrane,

Figure 5 shows a chamber with a variable valve to adjust the ratio of gas which are bypassed,

Figure 6 shows a chamber with an adjustable valve 30 where one part of the gas gets humidified while the other is heated,

Figure 7 shows a chamber where the dry gas entering chamber is pre-heated,

Figure 8 shows a chamber where the dry gas entering chamber is heated after leaving the chamber,

Figure 9 shows a chamber combined with an unheated, well insulated delivery tube,

Figure 10 shows construction of a tube incorporating flexible PTC elements in a parallel wire configuration, and

Figure 11 shows a humidifier configuration using the tube in Figure 10.

DETAILED DESCRIPTION OF THE INVENTION

Figure 1 illustrates a typical respiratory humidification system, comprised of three parts:

1) a humidification chamber located at a distance from the patient, which heats and substantially saturates gases flowing through it ;

2) a delivery system consisting of a flexible tube which carries humidified gases from the humidification chamber 1 to the gas outlet 5 ; and

3) a heater base which heats the humidification chamber 1 and provides measurement and control functions.

The gas to be humidified flows into the chamber 1 from port 4 and leaves the delivery system 2 at gas exit port 5. Gas from exit port 5 flows to a patient via a face mask or similar (not shown). The system is controlled using sensors located at positions 7 and 8 - typically temperature probes. Dry gases at the gas input 4 are heated and humidified by passing over the surface of hot water 6 in the chamber 1 so that they are substantially saturated with water vapour when they leave chamber 1 at exit port 10. Hot water 6 is heated by heater plate 9 and the amount of heating is controlled so that the gas reaches a predetermined temperature at exit port 10. This temperature is measured by sensor 7. Therefore the humidification chamber 1 acts to heat and humidify the medical gases so that they are substantially saturated at the output of chamber 1, and are at a predetermined temperature.

The gas delivery system 2 (also known as a delivery tube or breathing circuit) consists of a flexible tube 11 containing a heater 12, which may consist of a heated resistance wire. The gas from the humidification chamber 1 passes through the tube 11 and is heated by heater 12 to offset heat losses through the walls of tube 11. The amount of heating applied to heater 12 is regulated so that the gas reaches a predetermined temperature at gas outlet 5, as measured by sensor 8. The control temperature at sensor 8 is usually higher than the control temperature at sensor 7, so that the gas is heated along tube 11 to ensure that condensation doesn't occur in the tube.

The system as described has gas entering gas inlet 4 from a continuous flow gas source (not shown) and exiting the system through gas inlet 5. However the system is equally applicable where the gas source is a ventilator, which creates intermittent flow patterns to provide breaths to a patient. In this case gas outlet port 5 is connected directly to gas inlet port 16. The patient is connected to port 17 via an endotracheal tube or similar (not shown). During patient inspiration dry gases from the ventilator enter the system at inlet port 4, pass through chamber 1, delivery system 2, pass through wye-piece 13 and reach the patient through port 17. During patient exhalation gases pass back through port 17, through wye-piece 13, tube 14 and leave through gas outlet port 18. Tube 14 may also be heated by heater 15 to prevent condensation.

Absolute humidity sensing

Humidifiers incorporating humidity sensors for display or control have been described in the prior art, however all used humidity sensors which were positioned at the patient airway. The current work describes novel humidifier configurations incorporating a humidity generating chamber located at a position which is remote from the patient, a heated breathing circuit to transfer humidity to the patient, and humidity sensors to control the level of absolute or relative humidity supplied to the patient. These humidity sensors are to be located either:

1) at the chamber outlet only,
2) at both the chamber outlet and near the patient, or
3) near the patient only.

One aspect of the present invention would be to use a humidity sensor as sensor 7. The purpose of humidity sensor 7 is to determine the absolute amount of humidity which is being generated by chamber 1. Accordingly an absolute humidity sensor would be ideal for use as sensor 7, although the use of a relative humidity sensor with associated temperature sensor could equally be used. This system has the advantage of creating a controlled level of absolute humidity at chamber outlet 10, however this level of absolute humidity may not reach the patient if condensation is allowed to occur in tube 11.

An alternative system which would overcome this disadvantage is to use a second absolute humidity sensor at point 8 instead of a temperature sensor. The difference in absolute humidity between sensors 7 and 8 allows the humidifier to determine whether condensation is occurring between the two points. If the two absolute humidity sensors 7 and 8 read the same level of absolute humidity then no condensation is occurring in the tube. If the absolute humidity at sensor 7 is greater than at sensor 8, then the difference shows the rate of condensation that is occurring.

One control strategy would be to control the amount of heating provided to heater 12 so that the absolute humidity difference is reduced to zero. However the tube may still

contain mobile condensate because the humidity difference only describes the rate of condensation, not the absolute amount of condensate in the tube. Another control strategy is to remove this condensate and hence create a dry tube by heating heater 12 so that the rate of measured condensation is negative (i.e. condensation is being evaporated in tube 11) until the measured condensation rate reaches zero, indicating that all of the condensate has been removed. The amount of heating can then be reduced until the sensors show that condensation has just started to occur, then the heating can be increased slightly to the optimum level. Drying out of the tube may be a continuous process, or may be initiated at regular time intervals.

Another variation of the system shown in Figure 1 would be to use a temperature sensor for sensor 7 and an absolute humidity sensor at both points 7 and 8. This system is simpler than having an absolute humidity at both points 7 and 8. In operation the controller would have to adjust the amount of heating at heater 12 and heater plate 9 so that the correct level of absolute humidity was reached without condensate in delivery tube 12. In practice two separate control algorithms would be required, one to control the amount of heating occurring in tube 11 so that no condensation occurred, and another to control heater plate 9 so that the desired level of absolute humidity was generated in chamber 1. The two algorithms could work concurrently because the heater plate 9 will respond slower than heater 12, so quick changes in absolute humidity would indicate the action of heater 12. Sensor 7 provides a control point for heater plate 9, but may not be needed.

Low relative humidity chambers

All systems described so far have used a chamber 1 which attempts to humidify the gas leaving gas outlet 10 to a high level of relative humidity. While this condition isn't essential for the correct operation of the new humidification configurations just described because they use humidity control, it was essential for the prior art humidifier where control is purely based on temperature. However there are some advantages to be gained from using a chamber which heats gases to the correct absolute humidity, but at a low

relative humidity (i.e. the temperature of the gas is higher than the dewpoint of the gas, therefore the gas is not saturated).

The first advantage is that it is easier to design a heated delivery system to transport such a gas without condensation, since the gas doesn't need to be heated immediately after it enters the delivery tube to prevent condensation. Secondly, the use of low relative humidity gases leaving the chamber means that the heater element 12 can be rated at a lower power than would otherwise be the case, as the gas already has a higher energy content and can tolerate a greater loss of energy before the gas condenses in the tube 12. It may even be possible to use an unheated, well insulated breathing circuit instead of a heated breathing circuit if the chamber provides gas with enough energy. Note that low relative humidity chambers can only be used if the heating to the chamber is controlled using an absolute humidity sensor, not a temperature sensor, since otherwise the absolute humidity output would be too low.

To this end, some humidification chamber configurations which provide a high temperature, low relative humidity gas output are shown in Figures 2 - 8. Figure 2 shows a chamber which incorporates a metal element 20 (e.g. a spiral scroll shape), but without wicking paper attached. This provides both dry heating (via the metal element) and heated humidification from the heated water 21. With this configuration the chamber 19 provides gas which is not saturated because some of the heating provided to the gas is dry heating via the metal scroll. The relative humidity generated by the chamber is affected by the gas flow path, scroll shape, dimensions, and the water level, and so is not readily adjustable in use. However chamber 19 does give the condensate reducing advantages provided by a low relative humidity, controlled absolute humidity output.

Figures 3 and 4 are alternative humidification chambers which provide low relative humidity, high temperature gases at their output. Figure 3 shows a chamber using a porous material 22 (such as a porous ceramic) containing water 23 to provide a heating and humidifying function, while Figure 4 shows a chamber using a semipermeable membrane 24 to provide a barrier to the water 25 in the chamber. In both cases these

chambers provide dry heating via the porous or semipermeable material, as well as heated humidification from the water. In both cases the ratio of heating to humidifying is fixed and cannot be easily adjusted except by limiting the water supply.

Figures 5 to 8 show chambers that can supply gases at varying levels of relative humidity and temperature. In Figure 5 a variable valve 26 allows us to adjust the ratio of gas which passes through the dry bypass tube 27 to that which flows across the surface of the water 28. The bypass tube passes under the water to heat the gas. The two gas streams merge at the output 29. This is an example of a "parallel" system where the gas splits and takes two different paths to provide heating and humidification. In Figure 6 the gas is again split into two gas paths using an adjustable valve 30. One part of the gas gets humidified by passing across the water 31 in chamber 32, while the other is heated by heater 58, which surrounds tube 33. The gas paths merge at junction 34.

The angle of variable valves 26 and 30 in Figures 5 and 6 may be permanently set, may be manually adjustable, or may be automatically adjustable. One advantage of an automatically adjustable valve would be to provide a constant level of humidity out of the chamber when used with intermittent flow rates, for example when used with a ventilator. These flow patterns can be a problem because parts of the breath cycle contain less humidity than other parts, due to the chamber providing less humidity at higher flow rates. One way to overcome this problem is to measure the instantaneous flow rate using a fast response flow sensor, and then rapidly adjusting the angle of the variable valve. A more practical method of achieving this effect would be to spring-load valves 26 and 30 using springs 70 and 71. This would mean that low flow rates would mostly pass through the bypass tubes, while high flow rates would operate the spring-loaded valve and allow more gas to pass across the water in the humidification chamber. The angle of the spring-loaded variable valve could also be used by the humidifier to measure the gas flow rate.

Figures 7 and 8 show alternative series configurations for low relative humidity chambers, where the dry gas entering chamber 35 containing heated water 36 is either pre-heated via

heater 37 in Figure 7, or heated via heater 38 in Figure 8 after leaving the chamber. In both cases the heater provides dry heating to the gas and results in a low relative humidity, high temperature gas leaving outlet 39.

Any of the low relative humidity, high temperature chambers shown in Figures 2 to 8 can be used in conjunction with the humidity control schemes described previously in this patent, but not successfully with the prior art humidifier due to it being temperature controlled, not humidity controlled.

Insulated delivery tube

Another facet of the invention is shown in Figure 9. Here the low relative humidity, high temperature humidification system from Figure 8 has been combined with an unheated, well insulated delivery tube. The incoming gas enters at port 35 into the standard humidification chamber 36 containing water 37 which is heated by heater plate 38. The gas is substantially saturated in the chamber then leaves the chamber through gas outlet 39 and enters heated tube section 40 which heats the humid gas to a higher temperature, so that it has a low relative humidity. The gas then passes through tube 41 which has an insulating layer 42 around it. Preferably the insulating layer is a thin jacket of stagnant air which reduces heat loss. As the high temperature gas, low relative humidity gas passes through the insulating tube, a small amount of heat is lost through the tube walls, and therefore the gas cools. However the amount of heating applied to heater 40 is controlled, so that the gas is never allowed to cool below its dewpoint, which would result in condensation within tube 41.

Several different sensor configurations are proposed. Firstly, sensor 43 could be an absolute humidity sensor which controls heater plate 38 so that chamber 36 produces the desired level of humidity. In one embodiment sensor 45 is a temperature sensor, which controls heater 40 so that the gas passing sensor 45 remains at a certain desired temperature. If this temperature is greater than the dewpoint of the gas at sensor 43, then condensation should not occur in tube 41. However there may already be condensate in

tube 41 when the humidifier is turned on. If a humidity sensor is used for sensor 45 instead of a temperature sensor, then the level of condensate occurring in the tube 41 can be controlled. The algorithms described earlier in this patent for dual-humidity sensor control can be used with this system.

An alternative location for the absolute humidity sensor is at position 44 instead of 43. The absolute humidity here should be the same as at 43 because the gas has been heated and so hasn't lost any moisture. However there may be advantages to placing the absolute humidity sensor at 44, for instance due to better sensor operation in a low relative humidity environment. This location for the absolute humidity sensor can be used with either a temperature or absolute humidity sensor at location 45.

Humidifier configurations without any patient airway sensors

Yet another aspect of this patent relates to removing the need for a sensor at the patient airway. To remove this sensor safely, we must be certain that the gas entering the delivery tube has a safe level of temperature and absolute humidity, and that the surfaces inside the delivery tube do not exceed safe temperature levels. This implies a delivery tube that has a constant internal wall temperature.

It would be desirable, therefore, to have a heated delivery tube which self-regulates its temperature at a desired level. The heater could either be embedded in the wall of the delivery tube itself, or it could lie inside the lumen of the delivery tube, or it could be wrapped around the outside of the delivery tube. Such a heater could be made from positive temperature coefficient (PTC) material (such as "Winterguard" from Raychem Corp., Menlo Park, California USA), so that the resistance of the heater increases if the heater is hot, resulting in reduced power. However the delivery tube may pass through more than one environment, or may have localised drafts present on certain parts of the tube. However if the PTC elements are arranged in parallel, then the full benefit of the PTC heater can be envisaged. If the PTC elements are arranged in parallel, then the cold portions of the tube will have a lower resistance, which will result in more heat being

dissipated. Thus the tube will ten to regulate its own temperature.

Figure 10 shows construction of a tube incorporating flexible PTC elements in a parallel wire configuration. The tube 48 is made of a flexible PTC material, which has two low resistive strip connections, 46 and 47, on either side of it. This allows each portion of the tube to consist of short conducting segments of tube connected in parallel between conductors 46 and 47. These segments are represented by dotted lines encircling the tube in Figure 10.The conductors 46 and 47 are connected to adjustable voltage source 49, which may be AC or DC. The tube would have an outer layer (not shown) which provides electrical insulation and thermal insulation to the tube. Each longitudinal segment of the tube will be able to regulate its own temperature independently of the rest of the tube. To enhance this operation, it may be necessary to provide parallel slots 50 running perpendicular to the axis of the tube, to eliminate electrical cross-connection between the different PTC segments.

Although one specific PTC heated tube design has been envisaged and described, other PTC tube designs could be used. It may also be of advantage to create a PTC tube that has a differing temperature profile along its length rather than a constant temperature profile. The PTC design could also be extended to incorporate PTC heaters in other parts of the patient breathing circuit, such as the flexible extension tube which is usually connected between the Y-piece (port 17 of Figure 1) and the patient's endotracheal tube. A further extension of the PTC tube concept would be into a self-heated and temperature controlled endotracheal tube.

The PTC tube described in Figure 10 allows us to create a humidifier which doesn't use any sensor at the patient airway. Figure 11 shows a humidifier configuration using this tube. Gas enters humidification chamber 52 via inlet port 51 and is humidified by water 53, heated by heater plate 54. Absolute humidity sensor 55 controls the heater plate so that the gas passing sensor 55 is at a desired level of absolute humidity. PTC tube 56 is heated by an external voltage (not shown) so that the internal surface temperature is at a constant desired temperature, which is selected to be above the dewpoint of the gas. The

gas which leaves tube 56 at outlet 57 will therefore be near the temperature of the tube, and containing the desired level of absolute humidity which was controlled by absolute humidity sensor 55.

A variation of the system shown in Figure 11 would be to use a temperature sensor at position 55. Another variation of a tube with a constant internal wall temperature would a delivery tube with heated water or other fluid pumped through smaller conduits in the wall of the delivery tube. Since the heated fluid has a high specific heat relative to air, the temperature of the fluid remains fairly constant during passage through the delivery wall conduits.

Use of a sensor / heater manifold

Traditional humidifiers have tended to use sensors that are probe shaped, so that they can be inserted through specifically designed holes in the side of the breathing circuit to measure temperature. However the humidifier configurations that have been described in this patent incorporate many sensors around the chamber, so the use of a manifold 59 as shown in Figure 12 may be useful.

The humidification chamber 60 is a removable item which can be slid onto the humidifier base 61 as shown in Figure 12. As the chamber 60 is slid onto the humidifier base 61, its base makes contact with heater plate 62 and its inlet and outlet ports 63 and 64 make contact with holes 67 and 68 inside the manifold 59. Dry air to be humidified enters the manifold at port 65, passes out of the manifold through port 67, and flows through port 63 into the chamber 60, where it is humidified.

After leaving chamber 60 the humid gas passes through chamber port 64 into manifold port 68. Finally the humid gas leaves manifold 59 through port 66 and passes to the breathing circuit.

The manifold may be a separate, removable assembly, or it may be an integral part of the

humidifier base. It may contain temperature sensors, humidity sensors, flow sensors, or a heater element. These would be located inside the manifold 59 at positions 72 and 73. The manifold 59 may be heated to prevent condensation of humid gas. It could connect to both chamber ports 63 and 64 as described, or it may only connect to the outlet port 64. One advantage of using a manifold is that many sensors or heaters can be combined in a single, cleanable assembly, rather than requiring separate probes which need to be plugged into the breathing circuit. This simplifies connection and setup for the user. Another advantage of a manifold is that the incoming dry gas temperature and flow rate can easily be measured without additional probes and connections.

Variations on the described configurations

Although absolute humidity sensors have been described with all of the different humidification schemes described in this patent, relative humidity sensors could also be used. This may involve slightly different control algorithms to the ones described in this patent. Alternatively, a relative humidity sensor could be combined with a temperature sensor. This allows the absolute humidity to be calculated from relative humidity and temperature, rather than being measured directly.

All of the novel humidification schemes that have been described in this patent could be used with additional temperature sensors. These may provide additional benefits such as providing a safety backup in the event of a failed humidity sensor. Another benefit would be maintaining the temperature being delivered to the patient within certain limits so that the relative humidity is not too low, even though the absolute humidity was acceptable.

Similarly it may be useful to measure the air flowrate through the humidifier, as this is an important parameter which affects humidifier control. Therefore flow sensors could be incorporated within any of the previously described systems. One useful prior art flow sensor construction would be to use a sensor based on heat loss from a hot element in the airstream. If a heated humidity sensor is used, the amount of heating that is required for the sensor to achieve temperature can be used to determine the gas flow rate.

Infection control is a prime consideration when designing medical components. To prevent bacterial colonisation of the components in the humidification system, any parts which come in contact with the gas stream could be made out of antibacterial plastic. To prevent contamination of sensor probes, the probe ports could incorporate a disposable sheath which protects the probe from pathogens in the breathing circuit. This would be particularly applicable to temperature probes. In general humidity probes need to have contact with the gas stream so a disposable sheath would be inapplicable to humidity sensors, unless they worked on optical principles, or unless the sheath was made of water vapour permeable material, which did not allow the passage of pathogens. The protective sheath could be an integral part of a disposable breathing circuit.

DATED THIS 20 DAY OF March 2000
A.J. PARK & SON
PER V. J. Adams
AGENTS FOR THE APPLICANT

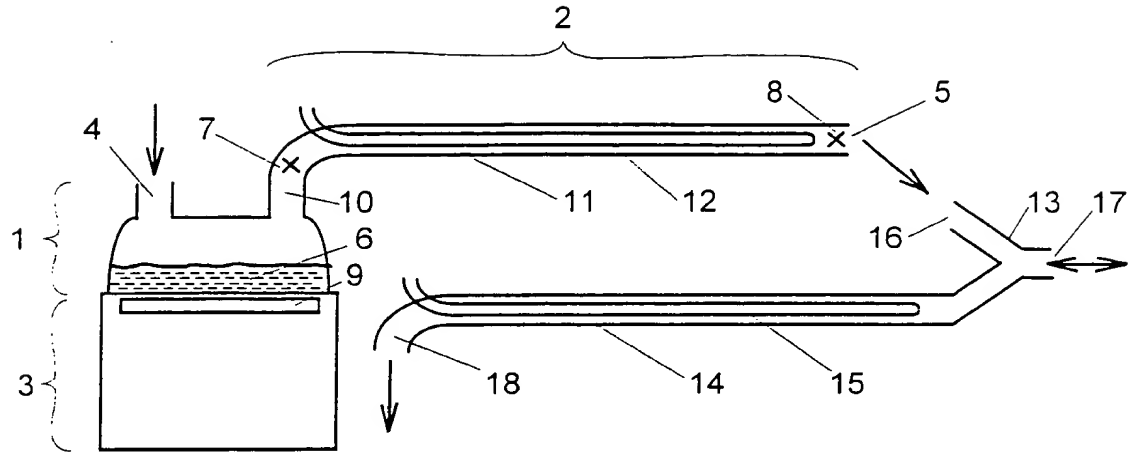

Figure 1

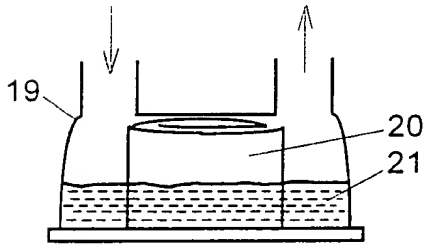

Figure 2

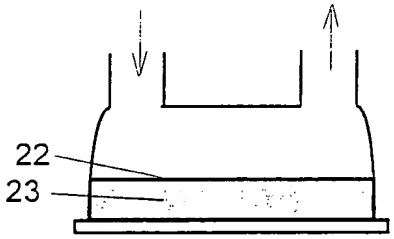

Figure 3

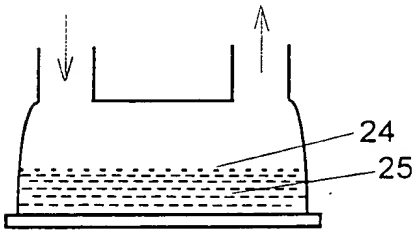

Figure 4

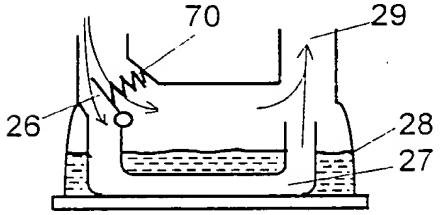

Figure 5

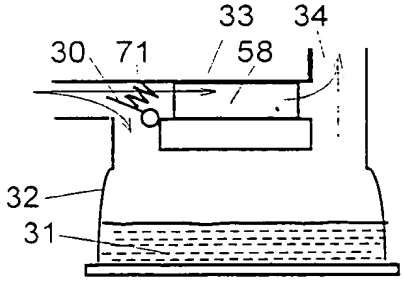

Figure 6

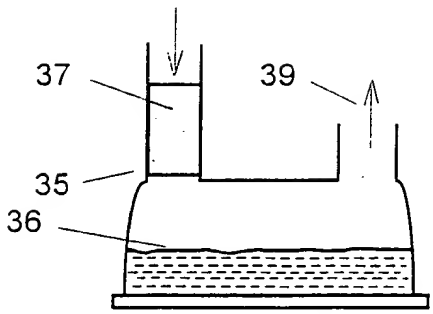

Figure 7

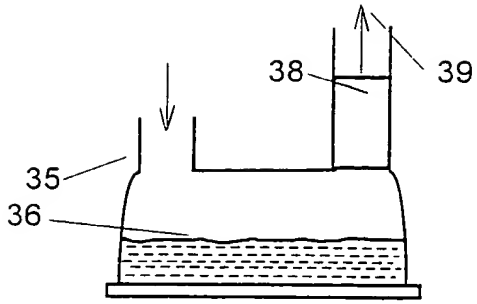

Figure 8

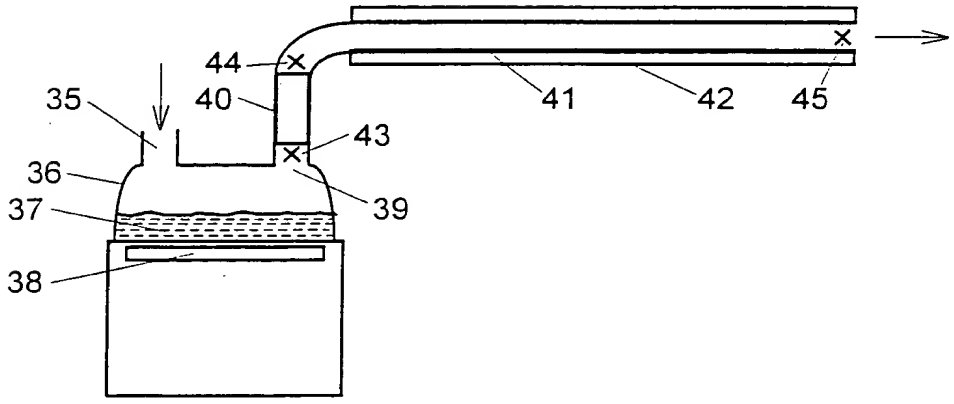

Figure 9

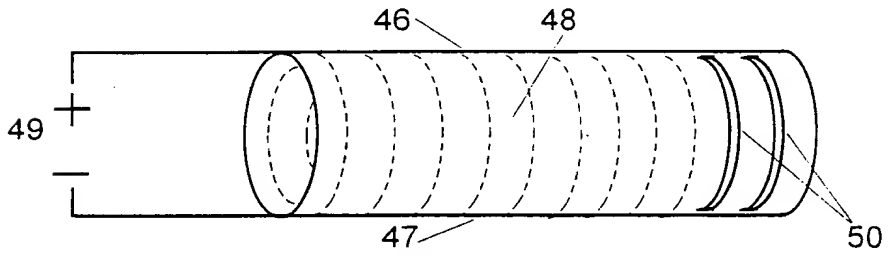

Figure 10

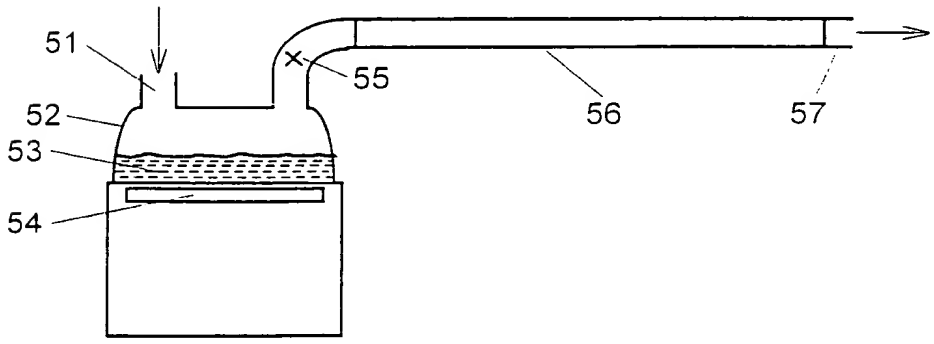

Figure 11

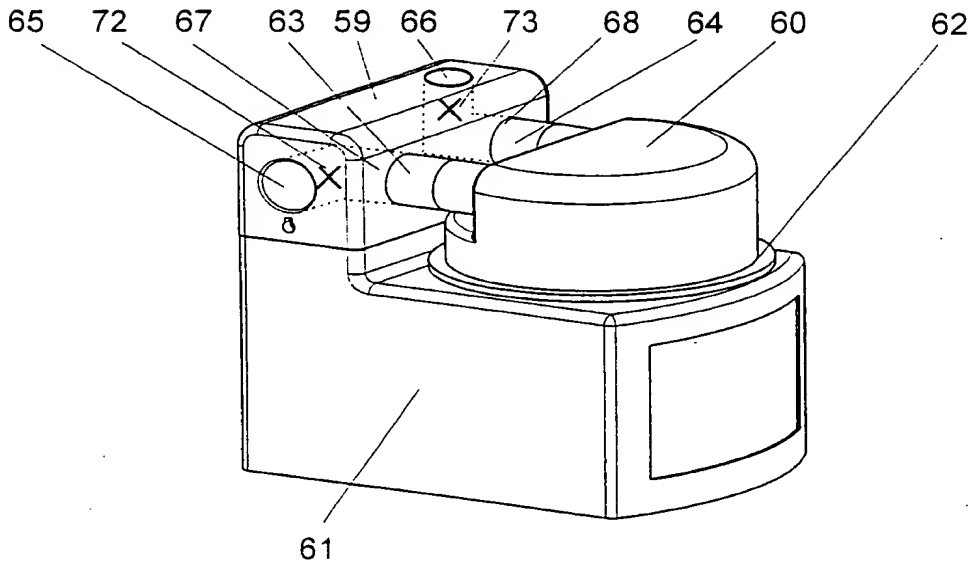

Figure 12